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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,953	07/31/2003	Bozidar Ferek-Petric	P0008856.04/LG10126	1782

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EXAMINER	
RAJAN, KAI	

ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
08/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/631,953	FEREK-PETRIC ET AL.	
	Examiner	Art Unit	
	Kai Rajan	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 42-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 42-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the reply filed June 16, 2010.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection. The reference cited below, Scheiner et al., was previously cited in the office action of September 19, 2007. In response, Applicant filed an affidavit asserting a conception date of October 21, 1999, which is the filing date of Scheiner et al. Upon further review, the affidavits filed December 19, 2007 are found insufficient. In particular, conception must be proven *prior* to the filing date of the reference. In addition, diligence must be proven from the date of conception until reduction to practice (see MPEP 715.07). Therefore, Applicant has not established a date of invention prior to the applied prior art.

Allowable Subject Matter

The indicated allowability of claims 3 – 6, 46, 47, and 49 – 59 is withdrawn in view of the rejections bellow.

Specification

The disclosure is objected to because of the following informalities: Continuing data in the specification must be updated. In paragraph 0002, the patent number assigned to application serial number 10/123,958 must be stated.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 6 and 42 – 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Scheiner et al. U.S. Patent No. 6,361,522, previously cited.

1. An interactive remote drug dose and physiologic response monitoring system in a patient under a prescriptive regimen to take a drug comprising:

a drug delivery device (Column 2 lines 9 – 22); and

an implantable medical device (IMD) (Column 1 lines 64 – 67, column 2 lines 1 - 8) in wireless communication with the drug delivery device, the IMD having means for receiving, from the drug delivery device, a communication indicating administration of a drug by the drug delivery device in compliance with a prescriptive regimen (Column 2 lines 24 – 34, column 3 lines 35 – 50, column 4 lines 24 – 52 IMD communicates wirelessly with drug delivery device and receives status signals including verification of drug delivery),

wherein the IMD monitors the patient's physiological signs subsequent to the administration of the drug (Column 2 lines 24 – 34, line 67, column 3 lines 1 – 34, column 4

lines 24 – 52 cardiac sensing and pacing electrodes continuously monitor the patient and determine drug effectiveness after delivery).

2. The system of claim 1, wherein the delivery device is chosen from one of the following: a pill box, a transdermal patch, a IV, an inhaler, an oral medicament dispenser, a subcutaneous implant, a drug pump, or a transcutaneous application (Column 1 lines 64 – 67, column 2 lines 1 – 8, column 5 lines 5 – 15 external drug delivery device includes oral medicine dispenser).

3. A drug delivery monitoring system comprising:

means for monitoring parameters of a drug delivery device (Column 2 lines 24 – 34, column 3 lines 35 – 50, column 4 lines 24 – 52 IMD communicates wirelessly with drug delivery device and receives status signals including verification of drug delivery);

means for communicating the monitored parameters with an implantable medical device (IMD) (Column 2 lines 24 – 34, column 3 lines 35 – 50, column 4 lines 24 – 52 IMD communicates wirelessly with drug delivery device and receives status signals including verification of drug delivery);

means for processing the monitored parameters (Column 2 lines 62 – 65, column 4 lines 24 – 52 implanted device includes a microprocessor that processes all received data); and

means for controlling the drug delivery device based on the processing of the monitored parameters (Column 3 lines 35 – 50, column 4 lines 24 – 52, column 5 lines 5 – 49 implantable

device controls drug delivery device in a closed loop fashion, receiving verifications from the drug delivery device and sensor data to control drug output).

4. The system of claim 3, further comprising: means for sensing physiological parameters through the IMD;

means for processing the sensed physiological parameters relative to a drug delivered by the drug delivery device (Column 3 lines 35 – 50, column 4 lines 24 – 52 implantable device processor processes received data and determines effectiveness of therapy delivered); and

means for controlling the drug delivery device in response to the processing of the sensed physiological parameters (Column 3 lines 35 – 50, column 4 lines 24 – 52, column 5 lines 5 – 49 implantable device controls drug delivery device in a closed loop fashion).

5. The system of claim 3, further comprising means for controlling a therapy delivered by the IMD based upon the sensed parameters (Column 1 lines 64 – 67, column 2 lines 1 – 8, lines 51 - 67, column 3 lines 1 – 50 drug delivery device incorporated in the implantable device, or pacing electrodes controlled by implantable device).

Claim 6 is rejected on the same basis as claims 1 and 3.

42. The system of claim 1, wherein the IMD modifies a therapy delivered by the IMD in response to the monitoring of the administration of the drug by the drug delivery device (Column

1 lines 64 – 67, column 2 lines 1 – 8, lines 51 - 67, column 3 lines 1 – 50 drug delivery device incorporated in the implantable device, or pacing electrodes controlled by implantable device).

43. The system of claim 1, wherein the IMD checks drug interaction in the patient subsequent to the administration of the drug (Column 3 lines 42 - 50, column 4 lines 39 – 52 effectiveness).

44. The system of claim 1, wherein the means for monitoring determines at least one parameter selected from the group consisting of:

drug intake by the patient in compliance with the prescriptive regimen;

whether the drug delivery device has administered a drug to the patient (Column 3 lines 42 - 50, column 4 lines 39 - 52);

a dosage of a drug administered by the drug delivery device (Column 3 lines 42 - 50, column 4 lines 39 – 52); and

an impact of administration of the drug on the IMD (Column 3 lines 42 - 50, column 4 lines 39 – 52 effectiveness).

45. The system of claim l, further comprising:

means for logging monitored parameters of the drug delivery device (Column 3 lines 42 - 50, column 4 lines 39 – 52 log created, stored, and transmitted).

46. The system of claim 1, wherein the drug delivery device includes a pill dispenser (Column 5 lines 5 – 15 oral medication device).

47. The system of claim 46, wherein the IMD determines at least one parameter of the drug delivery device selected from the group consisting of:

a number of pills in the pill dispenser; a number of pills taken by the patient via the pill dispenser; and a dosage of a drug taken by the patient from the pill dispenser (Column 3 lines 42 - 50, column 4 lines 39 – 52).

48. The system of claim 1, wherein the IMD is one of a neurostimulator or a cardiac stimulator (Column 3 lines 1 – 34 implantable device is a cardiac pacing device).

Claims 49 – 59 are rejected on substantially the same basis as citations listed above for claims 1 – 6 and 42 – 48.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

August 24, 2010